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REMARKS

In the Office action dated December 4, 2003, claims 1-10 were considered and rejected.

Claims 2 and 3 are canceled without prejudice, and claims 1 and 4-10 are amended and presented for reconsideration. Applicants respectfully submit that no new matter is introduced by the present Amendment. Support for amendments to claim 1 may be found at least at page 7, lines 10-15 and claim 3 as originally filed. Amendments are made to claims 4-10 to correct typographical errors.

Drawings

The Office action requires Applicants to furnish a drawing under 37 CFR 1.81. However, the Office action does not indicate the specific subject matter towards which the drawing should be directed. Applicants will file appropriate drawing(s) after allowable claims have been indicated.

Claim Rejections Under 35 U.S.C. § 112

The Office action rejects claims 1-10 under 35 U.S.C. § 112, first paragraph. Without acquiescing, but in the interest of advancing prosecution, Applicants hereby amend claim 1. Applicants respectfully request reconsideration and withdrawal of these rejections.

Claim Rejections Under 35 U.S.C. § 102

The Office action rejects claims 1, 4, and 5 under 35 U.S.C. § 102(b) over PCT publication WO 99/37216 by Gellman *et al.* (hereinafter "Gellman"). The Office action rejects claims 1 and 2 under 35 U.S.C. § 102(b) over U.S. Patent No. 5,961,528 to Birk *et al.* (hereinafter "Birk"). The Office action rejects claims 1 and 3 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,045,553 to Iverson *et al.* (hereinafter "Iverson"). The Office action rejects claims 1, 2, 4-7, and 9 under 35 U.S.C. § 102(b) over U.S. Patent No. 6,048,050 to Draenert (hereinafter "Draenert"). The Office action also rejects claim 1 and 3-5 under 35 U.S.C. § 102(b) over U.S. Patent No. 5,997,541 to Schenk (hereinafter "Schenk").

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Applicants respectfully traverse the § 102 rejections to the extent that they are maintained over amended independent claim 1 and claims depending therefrom.

Amended claim 1 recites a medical device comprising a push-in bone anchor and a protective cover. The cover comprises a brittle mass of biocompatible material. The push-in bone anchor is substantially encapsulated in the mass, and the cover breaks when the anchor is implanted into bone.

Gellman fails to teach or suggest all the elements of amended claim 1. Gellman fails to teach or suggest at least a protective cover comprising a brittle mass of biocompatible material or that such a cover breaks when the bone anchor is implanted into bone. Instead, Gellman describes covering a bone anchor with a balloon or a gelatin structure 890. See Gellman, page 3, lines 1-10; page 37, lines 17-22; and FIG. 43.

Birk also fails to teach or suggest all the elements of amended claim 1. According to Birk, part 46 in FIG. 3 is an insulator while part 44, shown in the same figure, is the tip of a skull pin which is needed for penetrating into a bone structure. See Birk, column 4, lines 52-65 and FIG. 3. Therefore, the blunt-ended insulator 46 cannot function as a bone anchor. Further, to the extent that the part 44 may function as a bone anchor, there is no protective cover taught or suggested in Birk. Birk fails to teach or suggest at least a protective cover, that the cover comprises a brittle mass of biocompatible material (column 5, line 13: "not brittle"), or that the cover breaks when the anchor is implanted into bone.

Iverson fails to teach or suggest all the elements of amended claim 1. First, Iverson describes a screw pin 10 which includes "a threaded portion 24" and not a push-in anchor as recited in amended claim 1. Iverson, column 3, lines 38-45; and FIG. 2.

Second, Iverson fails to teach or suggest that the protective cover breaks when the bone anchor is implanted into bone. In reference to a nonconductive layer 29, Iverson states that it is "bonded to at least the head portion 15 of the hybrid skull screw pin 10..." Iverson, column 4, lines 2-5. The verb "bond" is defined as "to cause to adhere firmly," in Webster's Ninth New Collegiate Dictionary, and as "to join securely, as with glue or

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cement," at www.dictionary.com.¹ Accordingly, the ceramic coating 29 in Iverson is not described as breaking upon implantation, but instead as remaining secured or adhered to the bone anchor. Further, the layer 29 is designed to function as an insulative layer to reduce heat conducted to a patient's skin, and therefore meant to maintain its structural integrity *after* the implantation. See Iverson, column 2, lines 17-29; and column 4, lines 9-11. Therefore, Iverson does not teach or suggest that the layer should break after implantation of the bone anchor.

Draenert also fails to teach or suggest all the elements of amended claim 1. First, Draenert does not teach or suggest a push-in bone anchor as recited in amended claim 1. Instead, Draenert describes a dowel-shaped implant 10 for a bone screw to screw into.

See Draenert, column 2, lines 53-63. Both the bone screw and the implant have a thread or a thread-like structure. See Draenert, column 7, lines 45-49; and FIG. 1. Second, Draenert fails to teach or suggest a protective cover comprising a brittle mass of biocompatible material or that the cover breaks when the bone anchor is implanted into bone. Instead, the implant 10 in Draenert "either spreads out when a screw is screwed in, or expands, or swells ... when it comes into contact with the body fluids in the bone, or it is screwed in itself." Draenert, column 2, lines 58-63; and column 5, lines 49-60.

Schenk also fails to teach or suggest all of the elements of Applicants' claim 1. First, Schenk fails to teach or suggest a push-in bone anchor. Instead, Schenk describes a bone screw 60 with a thread 61. See Schenk, column 5, lines 5-61; and FIG. 4. The washer 1 also has an external thread 9. See Schenk, column 3, lines 48-67; and FIGS. 1, 2, and 7. Second, Schenk does not teach or suggest substantially encapsulating the bone anchor. In contrast, the washer 1 in Schenk leaves a substantial portion of the bone screw 60 uncovered. See Schenk, FIGS. 4, 7, and 8. Third, Schenk does not teach or suggest that the cover breaks when the anchor is implanted into bone. See id. At least for the above reasons, Applicants respectfully request that all the 35 U.S.C. § 102(b) rejections of claim 1 and its dependent claims be reconsidered and withdrawn.

¹ A copy of relevant pages of the Webster's Ninth New Collegiate Dictionary and a printout of the relevant pages at www.dictionary.com are attached as Exhibit A.

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Claim Rejections Under 35 U.S.C. § 103

The Office action rejects claims 2 and 3 under 35 U.S.C. § 103(a) over Gellman in view of U.S. Patent No. 3,758,690 to Gittos *et al.* (hereinafter "Gittos"). The Office action further rejects claims 6-9 under 35 U.S.C. § 103(a) over Gellman.

Claims 2 and 3 are canceled. Gittos describes pharmacological properties in N-cyclopropyl-1-aminoindances. Gittos does not cure Gellman's deficiencies with regard to Applicants' amended claim 1. Claims 6-9 depend from claim 1, and because amended claim 1 is submitted to be patentable over Gellman, so are claims 6-9. Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. § 103(a).

CONCLUSION

Applicants respectfully request entry of this amendment and response, withdrawal of all bases of rejection, and allowance of claims 1 and 4-10 in due course for at least the reasons presented above. The Examiner is invited to telephone Applicants' under signed representative at (617) 248-7374 to discuss any outstanding issues.

Date: March 2, 2004 Reg. No.: 35,393

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-XOUNTY

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bo-le-ro \bo-le(a)r-(a)o\ n. pl-ros [Sp] (1787) 1: a Spanish dance characterized by sharp turns, stamping of the feet, and sudden pauses in a position with one arm arched over the head; also: music in \(^1/2\), time for or suitable for a bolero 2: a loose waist-length jacket open at the

front bolletus \bō-'lēt-əs\ n, pl-tus-es or-ti\-'lēt-,i\ [NL, genus name, fr. L, a fungus, fr. Gk bölitēs] (1601): any of a genus (Boletus) of soft pore fungi some of which are poisonous and others edible bollevar \bɔ-'lē-var, bäl-ɔ-vər\ n, pl-vares \bō-lò-'var-as, bō-li-\ or-vars [AmerSp bollvar, fr. Simön Bollvar] (ca. 1835) — see MONEY table bollevi-ano \bɔ-liv-ē-'an-\lò\ n, pl-nos [Sp] (ca. 1872): a former monetary unit of Bollvia replaced in 1963 by the peso boll \bolloning [ME] (15c): the pod or capsule of a plant (as cotton) bol-lard \bar bal-ərd, Brit also -ard\ n [perh. irreg. fr. bole] (ca. 1795) 1: a post of metal or wood on a wharf around which to fasten mooring lines 2: BITT 1 3 chiefly Brit: any of a series of short posts set at intervals to delimit an area (as a traffic island) or to exclude vehicular traffic

traffic bol·lix \'bäl-iks\ w [alter. of ballocks, pl. of ballock (testis), fr. ME, fr. OE bealluc — more at BALL] (1937): to throw into disorder; also: BUNGLE—usu. used with up — bollix n boll weevil n (1895): a grayish weevil (Anthonomus grandis) about \(V_i \) inch long that infests the cotton plant and feeds on the squares and bolls both as a larva and an adult boll-worm \'bol-worm\ n (1847): CORN EARWORM: also: any of several other moths or their immature stages which feed on cotton bolls as larvae.

bolo \bar{bolo} or their miniature stages which feet on botton bolis as larvae bolo \bar{bolo} \bar{bolo} n, pl bolos [Sp] (ca. 1899): a long heavy single-edged knife of Philippine origin bolo-gna \bar{bolo} \bar{bolo} -\bar{bolo} -\bar{bolo} = also \cdot -n(y) \rangle n [short for Bologna sausage, fr. Bologna, Italy (1596): a large smoked sausage of beef, veal, and pork bolom-efter \bar{bolo} -\bar{bolo} = also -n [Gk bol\bar{e} stroke, beam of light [fr. ballein to throw) \div \bar{E} -\bar{o} - + -meter] (1881): a very sensitive thermometer whose electrical resistance varies with temperature and which is used in the detection and measurement of feeble thermal radiation and is esp. adapted to the study of infrared spectra — bo-lo-met-ric \bar{bolo} -\bar{o} -\bar{o

necktie
Bolshevik \bolshə-,vik, 'bol-, 'bal-, -vēk\ n, pl Bolsheviks also Bolshevik \bolshə-'vik-ē, bol-, bal-, -vē-kē\ [Russ bol'shevik, fr. bol'-she larger] (1917) 1: a member of the extremist wing of the Russian Social Democratic party that seized supreme power in Russia by the Revolution of November 1917 2: COMMUNIST 3—Bolshevik adj bolshe-vism \bolshə-,viz-əm, 'bol-, 'bäl-\ n. often cap (1917) 1: the doctrine or program of the Bolsheviks advocating violent overthrow of capitalism 2: Russian communism
Bolshe-vist \-vost\ n or adj (1917): BOLSHEVIK
bolshe-vize \-vost\ n or adj (1917): to make Bolshevist — Bolshevize \-vize\ vize\ vize\ vize\ vige\ vize\ vise\ n or adj. often cap (1918): BOLSHEVIK

bolshe-vize \(\, \viz\) vi-vized; vizing (1919): to make Bolshevist — Bolshe-vize \(\triangle \) violi-sho-vize \(\triangle \) show. \(\triangle \) bolshie \(\triangle \) bolster \(\triangle \

from a volcano 4: a lead-lined container for radioactive material; FAILURE, FLOP (the play was a ~) 6 Brit: a large sum of money; Brit: a great success: HIT 8: a long pass in football "Ribomb wt (1688) 1: to attack with or as if with bombs: BOMBARD; to defeat decisively ~ wt 1: to fall flat: FAIL 2 slang: to move rapidly (~ed down the hill) — bomb-ing n "bom-bard bam-bard n [ME bomb-arde, fr. MF, prob. fr. L bomber (15c): a late medieval cannon used to hurl large stones "bom-bard bam-bard also bom-\ wt (1686) 1: to attack esp. with artillery or bombers 2: to assail vigorously or persistently (as with artillery or bombers 3: to assail vigorously or persistently (as with artillery and also bom-\ wt (1686) 1: to attack esp. with artillery artillery artillery or bombers 3: to subject to the impact of rapidly moving particles electrons or alpha rays) syn see ATTACK—bom-bard-ment \manni bom-bardier \manni bam-bar(r)-di(s)r\ n (1560) 1 a archaic: ARTILLER MAN b: a noncommissioned officer in the British artillery 2: bomber-crew member who uses the bombsight and releases the bombom-bar-don \mathbar-bar-don, bam-bar-don, bam-bar-don, at the bambar cotton padding, fr. MF bombom-bar \mathbar bardier, bombax cotton, alter. of L bombyc, bombyx, sill worm, silk, fr. Gk bombyk, bombyx [1589]: pretentious inflate speech or writing bom-bas-tik\ adi (1704): marked by or given to bom

worm, silk, fr. Gk bombyk. bombyx] (1589): pretentious inflate speech or writing bom-bas-tie \bar bom-bas-ti

bombed \'bamd\ adj (1969): affected by alcohol or drugs: DRUME

HIGH bomber \'bam-ar\ n (1915): one that bombs; specif: an airplane

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mold bombed \bambd \adj (1969) : affected by alcohol or drugs : DRUM HIGH HIGH bomber \bambd \adj (1969) : affected by alcohol or drugs : DRUM HIGH bomber \bambd \adj (1969) : one that bombs; specif : an airplane disigned for bombing and the property of the property of

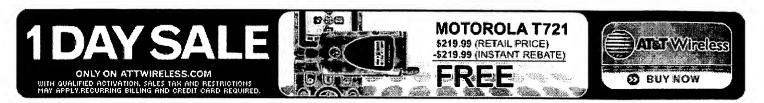
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Bond Pronunciation Key (bond), Julian. Born 1940.

American politician and civil rights leader who was elected to the Georgia legislature (1966) but temporarily barred from taking office because of his opposition to the Vietnam War.

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bond Pronunciation Key (bond)

n.

- 1. Something, such as a fetter, cord, or band, that binds, ties, or fastens things together.
- 2. Confinement in prison; captivity. Often used in the plural.
- 3. A uniting force or tie; a link: the familial bond.
- 4. A binding agreement; a covenant.
- 5. A duty, promise, or other obligation by which one is bound.

6.

- a. A substance or agent that causes two or more objects or parts to cohere.
- b. The union or cohesion brought about by such a

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substance or agent.

- 7. A chemical bond.
- 8. A systematically overlapping or alternating arrangement of bricks or stones in a wall, designed to increase strength and stability.
- 9. *Law*.
 - a. A written and sealed obligation, especially one requiring payment of a stipulated amount of money on or before a given day.
 - b. A sum of money paid as bail or surety.
 - c. A bail bondsman.
- 10. A certificate of debt issued by a government or corporation guaranteeing payment of the original investment plus interest by a specified future date.
- 11. The condition of taxable goods being stored in a warehouse until the taxes or duties owed on them are paid.
- 12. An insurance contract in which an agency guarantees payment to an employer in the event of unforeseen financial loss through the actions of an employee.
- 13. Bond paper.

v. bond·ed, bond·ing, bonds

v. tr.

- 1. To mortgage or place a guaranteed bond on.
- 2. To furnish bond or surety for.
- 3. To place (an employee, for example) under bond or guarantee.
- 4. To join securely, as with glue or cement.
- 5. To join (two or more individuals) in or as if in a nurturing relationship: "What bonded [the two men] who spoke rarely and have little personal rapport was patience and a conviction that uncontrolled inflation endangers... society" (Robert J. Samuelson).
- 6. To lay (bricks or stones) in an overlapping or alternating pattern.

v. intr.

- 1. To cohere with or as if with a bond.
- 2. To form a close personal relationship.

[Middle English, variant of band, from Old Norse. See bhendhin Indo-European Roots.]

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